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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,071	08/22/2003	Philip A. Swain	5673-66690-01	9609

7590 05/08/2007

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ART UNIT	**PAPER NUMBER**
1639	

MAIL DATE	DELIVERY MODE
05/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,071	SWAIN ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *100,101,103,104,109,111-113 and 117-140* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *100,101,103,104,109,111-113 and 117-140* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-99, 105-108, and 110 were canceled, claims 101-103 and 109 were amended, and new claims 111-124 were added in the amendment to the claims received on June 1, 2006.

The amendment to the claims received on February 16, 2007 amended claims 100-101, 118; canceled claims 102, 114-116; and added new claims 125-140.

Claims 100-101, 103-104, 109, 111-113, and 117-140 are currently pending and under consideration.

Priority

2. The present application claims status as a CON of 10/115,580 filed April 1, 2002 which is a CON of 09/882,803 filed June 14, 2001 which is a CON of 09/257,821 filed February 25, 1999 which is a CON of 08/720,487 filed September 30, 1996 (now U.S. Patent 5,876,727) which is a CIP of 08/563,673 filed November 28, 1995 (now U.S. Patent 5,760,184) which is a CIP of 08/414,971 filed March 31, 1995.

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/414,971, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 08/414,971 does not disclose nicotine metabolites of present Figure 19, haptens derived from nicotine, nicotine-1'-N-oxide, trans-3'-hydroxycotinine, or nicotine glucoronide.

The disclosure of the prior-filed application, Application No. 08/563,673, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 08/563,673 (U.S. Patent 5,760,184 does not disclose the specific nicotine metabolites of present Figure 19, haptens derived from nicotine, nicotine-1'-N-oxide, trans-3'-hydroxycotinine, or nicotine glucoronide.

Therefore, the priority date for the present claims is September 30, 1996.

Arguments and Response

4. Applicants allege that U.S. application 08/414,971 and U.S. application 08/563,673 provide support for present claims 125-140. However, neither U.S. application 08/414,971 nor U.S. application 08/563,673 recite hapten derivatives of nicotine as recited in independent claim 125.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on February 16, 2007 is being considered by the examiner with the following exceptions:

A. B02 and B03 were not considered because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

B. C04 and C15 are considered duplicates. C04 is simply the abstract of C03. C15 is a duplicate of C16.

Invention as Claimed

6. A hapten-carrier conjugate comprising at least one hapten derived from nicotine wherein the hapten is nicotine-1'-N-oxide, trans-3'-hydroxycotinine, nicotine glucoronide, or another nicotine derivative, at least one carrier containing a T cell epitope, and wherein the carrier and the hapten are linked by a group of chemical moieties CJ 0 – CJ11 wherein CJ 0 is carrier only and variations thereof.

Withdrawn Objections

7. The objection to the drawings regarding Figures 18A and 18B as not being described in the specification is withdrawn in view of the amendment to the specification received on February 16, 2007.

8. The objection to the disclosure regarding the description for Figure 4 is embedded in the text of the description for Figure 3b is withdrawn in view of the amendment to the specification received on February 16, 2007.

9. The objection to the claims 114-116 regarding Figure 19 is withdrawn due to the cancellation of the claims and the insertion of the chemical names into present claim 100 in the amendments to the claims received on February 16, 2007.

New Objections Necessitated by Amendment

10. Claims 100-101, 103-104, 109, 111-113, and 117-140 are objected to because of the following informalities: Claims 100 and 125 recite the limitation "CJ 10 as identified in the application as FIG. 2b". Either reciting the structure or the chemical formula in the claim is suggested. Appropriate correction is required.

MPEP § 2173.05 states the following: Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Claim Amendments

11. Applicants recite page 34, lines 24-27 which states "[p]reparation of the novel nicotine-carrier conjugates of the present invention are derived from nicotine and nicotine metabolites...Figure 19 shows a representation of nicotine and some of its metabolites" as support for present claim 125. Currently, claim 125 recites "a hapten-carrier conjugate comprising at least one hapten derived from nicotine, wherein the hapten is nicotine". Since the present claim states a hapten derived from nicotine, the claim amendment does not presently add new matter. However, a nicotine-carrier conjugate may be considered new matter. Please refer to

the Merriam-Webster Online Dictionary entry for "derive" (printed May 2, 2007; 1 page) wherein derived means to obtain from a parent substance thus a hapten derived from nicotine does not encompass nicotine as the actual hapten.

New Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 125-140 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claim 125 recites the limitation "a hapten-carrier conjugate comprising at least one hapten derived from nicotine, wherein the hapten is nicotine". One of skill in the art would not be able to determine the scope of the presently claimed invention because a hapten derived from nicotine cannot also be nicotine. Thus, the presently claimed invention is indefinite. Please refer to the Merriam-Webster Online Dictionary entry for "derive" (printed May 2, 2007; 1 page) wherein derived means to obtain from a parent substance thus a hapten derived from nicotine does not encompass nicotine as the actual hapten.

Withdrawn Rejection

14. The rejection of claims 100, 103, and 114 are rejected under 35 U.S.C. 102(e) as being anticipated by Manian et al. U.S. Patent 5,843,680 filed April 19, 1995 is withdrawn in view of the claim amendments received on February 16, 2007 (i.e. nicotine-1'N-oxide, trans-3'-hydroxycotinine, and nicotine glucoronide).

Maintained Rejection

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Please note: the rejection has been altered to reflect the claim amendments received on February 16, 2007.

Claim Rejections - 35 USC § 102

16. The rejection of claims 100, 103, 111, 125, and 127 are rejected under 35 U.S.C. 102(b) as being anticipated by Walling et al. U.S. Patent 5,164,504 issued November 17, 1992.

For present claims 100 and 125, Walling et al. teach nicotine derivatives, cotinine, or cotinine derivative (e.g. nicotine derivative/metabolite, nicotine) hapten-carrier conjugates wherein the hapten is cotinine (i.e. cotine), trans-3'-cotinine (i.e. trans-3'-hydroxycotinine), and cotinine-N-oxide (i.e. nicotine-1'-N-oxide) which are metabolites of nicotine, the carrier can be a protein or a peptide including poly(amino acid), bovine serum albumin, albumin, serum protein, keyhole limpet hemocyanin, egg ovalbumin, bovine gamma globulin, thyroxine binding globulin, and polylysine (e.g. T-cell epitopes), and the carrier is covalently bound to the hapten via direct linkage (i.e. CJ 0) or (CH2)2CONH (i.e. CJ 6) (please refer to the Abstract; Formulas I, IV, V, VI, , VII, VIII, IX, X, XI, XII, XV, and XVI; columns 1-8; Examples 1-8; claims 1-6; Table 1). In addition, Walling et al. teach utilizing S, O, and NH molecules in the branches joining the hapten and the carrier (please refer to columns 2-6).

For present claims 103, 111, and 127, Walling et al. teach carriers that are proteins or peptides (please refer to columns 2-6).

Therefore, the presently claimed invention is anticipated by the teachings of Walling et al.

Arguments and Response

17. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Walling et al. for claims 100, 103, and 111 were considered but are not persuasive for the following reasons.

Applicants contend that Walling et al. does not teach haptens as nicotine-1'-N-oxide, trans-3'-hydroxycotinine, or nicotine glucoronide. In addition, applicants contend that claims 125-140 should not be rejected by Walling et al. because Walling et al. fail to teach hapten-carrier conjugates wherein the hapten is nicotine.

Applicants' arguments are not convincing since the teachings of Walling et al. anticipate the hapten-carrier conjugate of the instant claims. Walling et al. teach cotinine or cotinine derivative (e.g. nicotine derivative/metabolite) hapten-carrier conjugates wherein the hapten is cotinine (i.e. cotine), trans-3'-cotinine (i.e. trans-3'-hydroxycotinine), and cotinine-N-oxide (i.e. nicotine-1'-N-oxide) which are metabolites/derivatives of nicotine (please refer to Table 1 and columns 2-8). In addition, independent claim 125 claims "a hapten-carrier conjugate comprising at least one hapten derived from nicotine, wherein the hapten is nicotine" which is interpreted as a nicotine derivative-carrier conjugate wherein a nicotine derivative can not be nicotine (please refer to the Merriam-Webster Online Dictionary entry for "derive" (printed May 2, 2007; 1 page) wherein derived means to obtain from a parent substance thus a hapten derived from nicotine does not encompass nicotine as the actual hapten).

New Rejections due to Applicants Disclosure in the IDS

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 100-101, 103-104, 109, 111-113, 117, 120-132, and 136-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walling et al. U.S. Patent 5,164,504, Holmgren et al. Am. J. Trop. Med. Hyg. 50(5) suppl.: 42-54, 1994 (provided by applicants in IDS), and Illum WO 94/27576 published December 8, 1994.

For present claims 100, 104, 125, and 128, Walling et al. teach cotinine or cotinine derivative (e.g. nicotine derivative/metabolite) hapten-carrier conjugates wherein the hapten is cotinine (i.e. cotine), trans-3'-cotinine (i.e. trans-3'-hydroxycotinine), and cotinine-N-oxide (i.e. nicotine-1'-N-oxide) which are metabolites of nicotine, the carrier can be a protein or a peptide including poly(amino acid), bovine serum albumin, albumin, serum protein, keyhole limpet hemocyanin, egg ovalbumin, bovine gamma globulin, thyroxine binding globulin, and polylysine (e.g. T-cell epitopes), and the carrier is covalently bound to the hapten via direct linkage (i.e. CJ 0) or (CH2)2CONH (i.e. CJ 6) (e.g. more than one hapten coupled to carrier; please refer to the Abstract; Formulas I, IV, V, VI, , VII, VIII, IX, X, XI, XII, XV, and XVI; columns 1-8; Examples 1-8; claims 1-6; Table 1). In addition, Walling et al. teach utilizing S, O, and NH molecules in the branches joining the hapten and the carrier (please refer to columns 2-6).

Furthermore, Walling et al. teach utilizing the hapten-carrier conjugates as immugens and eliciting immune responses in various animals (please refer to column 6).

For present claims 101 and 126, Walling et al. teach n = 2 and n = 0 or 1 (e.g. n = 3 to 20; please refer to Examples 6-7; Formulas XV and XVI; columns 2-6).

For present claims 109, 123, 131, and 139, Walling et al. teach (i.e. pharmaceutically acceptable excipient; please refer to).

For present claims 103, 111, and 127, Walling et al. teach carriers that are proteins or peptides including BSA; albumins, globulins, lipoproteins, etc. (please refer to columns 2-6).

For present claims 109, 123, 131, and 139, Walling et al. teach various excipients (i.e. pharmaceutically acceptable excipient; please refer to Examples 1-3 and 6-8).

For present claims 117, 124, 132, and 140, Walling et al. teach pristine (i.e. adjuvant; please refer to column 7, lines 24-31).

However, Walling et al. does not teach cholera toxin B or parentaternal, oral, dermal, or topical administration.

For present claims 112-113, 117, 120, 124, 129-130, 132, 136, and 140, Holgren et al. teach utilizing cholera toxin B as a carrier/immunogen/adjuvant particularly when antigen/hapten is administered at mucosal surfaces (e.g. auxiliary agent; please refer to abstract; introduction section).

For present claims 121-123 and 137-138, Illum teaches parateral, oral, dermal, and topical administration of nicotine, pharmaceutically acceptable salts of nicotine, or nicotine derivatives and various carriers, excipients, and auxiliary agents (please refer to pages 2-9, 12-17; Examples 1-8).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the nicotine derivative-carrier conjugate taught by Walling et al. with the carrier taught by Holgren et al. and the specific route of administration taught by Illum.

One having ordinary skill in the art would have been motivated to do this because Illum et al. teaches that nicotine and nicotine derivatives is easily absorbed nasally, orally, and dermally (please refer to pages 2-3). In addition, Holgren et al. teach that cholera toxin can be utilized as a carrier (please refer to abstract). Furthermore, the specific carrier or route of administration of the hapten-carrier conjugate would be an experimental design choice based on what the hapten-carrier conjugate was to be utilized for (e.g. which carrier/route produces best immune response for the specific application, which carrier/route delivers the most hapten to a desired location, etc.).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the nicotine derivative-carrier conjugate taught by Walling et al. with the carrier taught by Holgren et al. and the specific route of administration taught by Illum because Illum teaches parateral, oral, dermal, and topical administration of nicotine, pharmaceutically acceptable salts of nicotine, or nicotine derivatives and various carriers, excipients, and auxiliary agents (please refer to pages 2-9, 12-17; Examples 1-8).

Therefore, the modification of the nicotine derivative-carrier conjugate taught by Walling et al. with the carrier taught by Holgren et al. and the specific route of administration taught by Illum render the instant claims *prima facie* obvious.

Maintained Rejections

20. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Please note: the rejections have been altered to reflect the claim amendments received on February 16, 2007.

Double Patenting

21. Claims 100-101, 103-104, 109, 111-113, 117-140 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-5, 8-12, and 17-18 of U.S. Patent No. 5,876,727. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions as claimed in U.S. Patent No. 5,876,727 claim nicotine or nicotine-derived haptens conjugated to a carrier and pharmaceutical compositions of the hapten-carrier.

For present claims 100 and 125, U.S. Patent No. 5,876,727 claims a nicotine hapten-carrier conjugate comprising the structure shown in Figures 17b and 18 (e.g. nicotine derivative hapten wherein chemical moieties may be at positions A-F and not simply utilized as a linker between the hapten and the carrier) and side chains (e.g. branch) of CJ0 (for example Q), 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, 11 (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claim 1).

For present claims 101 and 126, U.S. Patent 5,876,727 claims n is from 3 to 20 (e.g. within the range of about 2 to about 20; please refer to claim 1).

For present claims 103, 127, and 129-130, U.S. Patent 5,876,727 claims carriers of cholera toxin, diptheria toxin, tetanus toxoid, pertussis toxin, ricin B subunit, retrovirus

nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, or vesicular stomatis virus nucleocapsid protein (e.g. proteins, peptides, bacterial toxins, subvirals; please refer to claim 1).

For present claims 104 and 128, U.S. Patent 5,876,727 claims at least two haptens coupled to the carrier (e.g. greater than one hapten; please refer to claim 2).

For present claims 109 and 131-132, U.S. Patent 5,876,727 claims a pharmaceutically acceptable carrier, an aqueous solution at a physiologically acceptable pH, and adjuvants (e.g. pharmaceutically acceptable excipient; please refer to claims 8-11).

For present claim 111, U.S. Patent 5,876,727 claims carriers of cholera toxin, diptheria toxin, tetanus toxoid, pertussis toxin, ricin B subunit, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, or vesicular stomatis virus nucleocapsid protein (e.g. proteins, peptides, bacterial toxins, subvirals; please refer to claim 1).

For present claim 112, U.S. Patent 5,876,727 claims carriers of cholera toxin, diptheria toxin, tetanus toxoid, pertussis toxin, ricin B subunit, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, or vesicular stomatis virus nucleocapsid protein (please refer to claim 1).

For present claim 113, U.S. Patent 5,876,727 claims carriers of cholera toxin, diptheria toxin, tetanus toxoid, pertussis toxin, ricin B subunit, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, or vesicular stomatis virus nucleocapsid protein (please refer to claim 1).

For present claim 117, U.S. Patent 5,876,727 claims adjuvants (please refer to claims 9-10).

For present claims 118 and 133, U.S. Patent 5,876,727 claims alum, MF59, or RIBI adjuvants (please refer to claims 9-10).

For present claims 119 and 134-136, U.S. Patent 5,876,727 claims the alum genus (e.g. aluminum hydroxide or aluminum phosphate; please refer to claims 9-10).

For present claims 120 and 136, U.S. Patent 5,876,727 claims pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. auxiliary agent or supplementary active compound; please refer to claims 8-11).

For present claims 121 and 137, U.S. Patent 5,876,727 claims parenteral administration to a mammal (e.g. human; please refer to claims 12 and 17).

For present claim 122 and 138, U.S. Patent 5,876,727 claims oral administration (please refer to claims 12 and 18).

For present claims 123 and 139, U.S. Patent 5,876,727 claims pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. excipient; please refer to claims 8-11).

For present claims 124 and 140, U.S. Patent 5,876,727 claims adjuvants (please refer to claims 9-10).

Therefore, the claims of U.S. Patent 5,876,727 render the present claims unpatentable.

Arguments and Response

22. Applicants' arguments directed to the rejection of present claims 100-101, 103-104, 109, 111-113, 117-140 as being unpatentable on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4-5, 8-12, and 17-18 of U.S. Patent No. 5,876,727 were considered but are not persuasive for the following reasons.

Applicants "request that the rejection be held in abeyance until such time as the examiner indicates there is allowable subject matter".

Applicants' arguments are not convincing since the rejection cannot be held in abeyance. Please refer to MPEP § 714.02 and 37 CFR 1.111 which states "[I]f the reply is with respect to an application, a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated" (emphasis added).

23. Claims 100-101, 103-104, 109, 111-113, and 117-140 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 43-45, 47-50, 52-54, 56-65, and 74-82 of copending Application Nos. 11/066,718; 11/472,215; 11/472,216; 11/472,217; 11/472,218; 11/472,219; 11/472,220; 11/472,222; and 11/472,223. Please note that the previously mentioned Patent Applications contain the same or similar claim sets, therefore, a single provisional nonstatutory obviousness-type double patenting rejection is being made for all of the applications. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions claimed in U.S. Patent applications 11/066,718; 11/472,215; 11/472,216; 11/472,217; 11/472,218; 11/472,219; 11/472,220; 11/472,222; and 11/472,223 (referred to as simply U.S. Patent Applications) claim hapten-carrier conjucates and pharmaceutical compositions.

For present claims 100 and 125, U.S. Patent Applications claim a nicotine hapten-carrier conjugate comprising the structure shown in Fig. 17b (e.g. nicotine derivative hapten) and branches of CJ0 (for example Q), 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8,

8.1, 9, 10, 11; and Y (e.g. for the CJ structures) is S, O, or NH (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claims 43 and 65).

For present claims 101 and 126, U.S. Patent Applications claim n is from 3 to 20 (please refer to claims 43 and 65).

For present claims 103, 127, 129, and 130, U.S. Patent Applications claim carriers of proteins, peptides, multiantigenic peptides, cholera toxin, diptheria toxin, tetanus toxoid, pertussis toxin, pertussis filamentous hemagglutinin, shiga toxin, ricin B subunit, abrin, sweet pea lectin, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, cow pea mosaic virus, cauliflower mosaic virus, vesicular stomatis virus nucleocapsid protein, recombinant pox virus subunits and vectors, Semliki forest virus vectors, Pseudomonas endotoxin, multiantùgenic peptides (MAP), yeast virus-like particles (VPLs), malarial protein antigen, and microspheres (please refer to claims 47-50).

For present claims 104 and 128, U.S. Patent Applications claim at least one or at least two haptens coupled to the carrier (please refer to claims 44-45 and 53-54).

For present claims 109 and 131, U.S. Patent Applications claim a pharmaceutically acceptable excipient (please refer to claim 56).

For present claim 111, U.S. Patent Applications claim carriers of proteins, peptides, multiantigenic peptides, cholera toxin, diptheria toxin, tetanus toxoid, pertussis toxin, pertussis filamentous hemagglutinin, shiga toxin, ricin B subunit, abrin, sweet pea lectin, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, cow pea mosaic virus, cauliflower mosaic virus, vesicular stomatis virus nucleocapsid protein, recombinant pox virus subunits and

vectors, Semliki forest virus vectors, Pseudomonas endotoxin, multiantùgenic peptides (MAP), yeast virus-like particles (VPLs), malarial protein antigen, and microspheres (e.g. bacterial toxins, subvirals, allergens; please refer to claims 47-50).

For present claim 112, U.S. Patent Applications claim carriers of cholera toxin, diptheria toxin, tetanus toxoid, pertussis toxin, pertussis filamentous hemagglutinin, shiga toxin, Pseudomonas endotoxin, ricin B subunit, abrin, sweet pea lectin, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, cauliflower mosaic virus, vesicular stomatis virus nucleocapsid protein, recombinant pox virus subunits and vectors, Semliki forest virus vectors, yeast virus-like particles (VPLs) (please refer to claims 47-50).

For present claim 113, U.S. Patent Applications claim carriers of cholera toxin, diptheria toxin, tetanus toxoid, pertussis toxin, pertussis filamentous hemagglutinin, shiga toxin, Pseudomonas endotoxin, ricin B subunit, abrin, sweet pea lectin, retrovirus nucleoprotein, rabies ribonucleoprotein, tobacco mosaic virus, cauliflower mosaic virus, vesicular stomatis virus nucleocapsid protein, recombinant pox virus subunits and vectors, Semliki forest virus vectors, yeast virus-like particles (VPLs) (please refer to claims 47-50).

For present claims 117 and 132, U.S. Patent Applications claim adjuvants (please refer to claims 58-59).

For present claims 118 and 133, U.S. Patent Applications claim alum, MF59, or RIBI adjuvants (please refer to claims 58-59).

For present claims 119 and 134-135, U.S. Patent Applications claim the alum genus (e.g. aluminum hydroxide or aluminum phosphate; please refer to claims 58-59).

For present claims 120 and 136, U.S. Patent Applications claim pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. auxiliary agent or supplementary active compound; please refer to claims 56-60 and 74).

For present claims 121 and 137, U.S. Patent Applications claim parenteral administration to a mammal (e.g. human; please refer to claims 61-64, 75-79, and 81).

For present claims 122 and 138, U.S. Patent Applications claim oral administration (please refer to claims 80 and 82).

For present claims 123 and 139, U.S. Patent Applications claim pharmaceutically acceptable excipient (please refer to claim 56).

For present claims 124 and 140, U.S. Patent Applications claim adjuvants (please refer to claims 58-59).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Arguments and Response

24. Applicants' arguments directed to the rejection of present claims 100-101, 103-104, 109, 111-113, 117-140 as being unpatentable on the ground of nonstatutory obviousness-type double patenting (provisional) as being unpatentable over claims 43-45, 47-50, 52-54, 56-65, and 74-82 of copending Application Nos. 11/066,718; 11/472,215; 11/472,216; 11/472,217; 11/472,218; 11/472,219; 11/472,220; 11/472,222; and 11/472,223 were considered but are not persuasive for the following reasons.

Applicants "request that the rejection be held in abeyance until such time as the examiner indicates there is allowable subject matter".

Applicants' arguments are not convincing since the rejection cannot be held in abeyance. Please refer to MPEP § 714.02 and 37 CFR 1.111 which states "[I]f the reply is with respect to an application, a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated" (emphasis added).

Conclusion

25. Applicant's amendment and/or IDS necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS
May 2, 2007

MARK L. SHIBUYA
PRIMARY EXAMINER